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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,627	10/09/2001	Thomas Conrad Mack	N1388-017	4202

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CENTENNIAL, CO 80112

EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/971,627

Applicant(s)

MACK ET AL.

Examiner

Medina A Ibrahim

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-14 and 33-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9, 11 and 37-44 is/are allowed.
- 6) ☒ Claim(s) 12-14, 33-36 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants' response filed 05/29/03 in reply to the Office action mailed 1/30/03 and amendment A have been entered. Claims 10 and 15-32 have been cancelled. New claims 33-45 have been added. Therefore, claims 1-9 and 33-45 are pending and are under examination.

All previous rejections and objections not stated below have been withdrawn.

New Matter

Claims 33 and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

The claims are drawn to a hybrid corn seed wherein "fifty percent of its genetic material originates from the pollen of claim 3 " and "from the ovule of claim 4", respectively. However, support for the phrase "fifty percent of its genetic material" cannot be found in the specification or in the claims as originally filed. Therefore, the phrase "fifty percent of its genetic material" is considered to be a new matter. Applicant is requested to point to support for the phrase in the originally filed or to delete the NEW MATTER in response to this rejection.

Claim Rejections - 35 USC § 112, 2nd paragraph

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Claims 33-36 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33 and 34 are indefinite because what is encompassed by a "genetic material" is unclear. The specification fails to describe the phrase, and hence, the phrase is open to variety of interpretations. Therefore, the metes and bounds of the claims are unclear.

Claim 35 and 45 are indefinite in the recitation of "corn endosperm with improved nutritional quality" and "corn endosperm quality", respectively. It is unclear what nutritional qualities are intended and how they are improved. The specification fails to describe what constitutes an "improved nutritional quality", and "corn endosperm quality", and hence, the metes and bounds of the claims are unclear. In addition, "improved" is a relative term lacking comparative basis. Dependent claim 36 is included in the rejection.

While Applicant may use his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "single gene conversion" in claim 45 is used by the claim to mean "moving a desired morphological and physiological characteristics via the backcrossing technique or via genetic engineering," (see page 8, paragraph 20 of the specification) while the accepted meaning is "nonreciprocal event that occurs at or near the crossover point during reciprocal recombination". (Darnell et al

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1990, In Molecular Cell Biology, Scientific American Books, Inc. New York, New York, specifically page 478). The use of the term ---transgene--- would obviate the rejection.

Claim Rejections - 35 USC § 112, Enablement

Claims 35-36 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method of producing a transgenic corn plant having corn endosperm with improved nutritional quality by transforming a corn plant of the inbred 2JK221 with a single gene conversion that confers improved nutritional quality and transgenic corn plant produced by said method.

Applicant has not provided guidance for a multitude of genes that confer improved nutritional quality or a method of transforming a plant with said multitude genes to improve a multitude of nutritional qualities. While transformation of a plant with a transgene for a desired agronomic trait is well within the level of one skill in the art, there is no known single gene that confers "improved nutritional quality" as recited in the claims. For example, improving nutritional quality of corn endosperm may include increasing or decreasing one or more amino acids, carbohydrates or fatty acid contents in corn seed. However, the specification does not provide guidance regarding what

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nutritional qualities, with what genes and how they might be improved. Absent such specific guidance, one skilled in the art that wishes to practice the claimed invention is left with trial and error experimentation considered undue. Therefore, the claimed invention is not enabled.

Written Description

Claims 12-14, 33-36 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons as set forth in the last Office action mailed 01/30/03, for claims 12-14. Applicant's response filed 05/30/03 didn't address the rejection, and therefore, the rejection is maintained for claims 12-14.

Claims 33-34 are directed to a hybrid seed having fifty percent of its genetic material from the plant of the inbred line 2JK221, and the other fifty percent of its genetic material is from an unknown inbred corn plant. The genotypic or phenotypic description of the second half of the genetic material of the claimed F1 hybrid plants is not known. In addition, since each parent line contributes a set of alleles and these two sets of alleles interact in a variety of ways (influenced by the environment) to determine the phenotype of the progeny, one cannot predict how the genes of the known parent 2JK221 will affect the phenotype of the F1 hybrid. It is not known how the known (fifty percent) genotype would react with the environment or with other genes in the genome. The specification, page 3, lines 6-16, discusses the complexity of inheritance and states

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" (t)he inbred lines which are developed are unpredictable. This unpredictability is because the breeder's selection occurs in unique environments, with no control at the DNA level (using conventional breeding procedures)..... A breeder of ordinary skill in the art cannot predict the final resulting lines he develops." The specification further states, "(t)he same breeder cannot produce the same line twice by using the exact same original parents and the same selection techniques". Therefore, it is likely that F1 hybrids produced from each cross with 2JK221 may be genetically distinct. A substantial variation in phenotypes and/or genotypes is expected among F1 hybrids. Therefore, the description of the genotype of a first parent by deposit, along with a description of the phenotypic characteristics of said one parent is insufficient to describe a hybrid produced by crossing said first parent with any and all second parents which are not described.

Claims 35-36 and 45 are rejected because Applicant has not described the broad class of transgenes (or single gene conversion) that confer any and all types of improved endosperm nutritional quality, and therefore, there is doubt as to whether Applicant was in possession of all corn plants with improved nutritional quality at the time of filing. Consequently, the written description requirement is not satisfied.

Remarks

Claims 1-9, 11 and 37-44 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Thursday from 8:30 AM to 5:00 PM and every other Friday from 9:00AM to 5:00PM

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

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Mai



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